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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,175	04/13/2004	Mary J. Ruwart	RUW-001	6078

7590 08/31/2006

Nancy Lord Johnson, Ltd.
1970 N. Leslie Rd., No. 220
Pahrump, NV 89060

EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	PAPER NUMBER
1661	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,175	RUWART, MARY J.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment of July 14, 2006 is hereby acknowledged and entered.

Status of Application

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

Election/Restrictions

Applicant has cancelled the claims drawn to different inventions, in the reply dated August 19, 2005, so the restriction requirement is moot.

Claims Pending

Applicant has cancelled claims 2, 18-29. Claims 1 and 3-17 are examined.

Claim Objections

Claims 1, 4, 5, 7 and 10 are objected to because of the following informalities: claims 1, 7 and 10 recite the term "omega-3" while claims 4 and 5 recite "3-omega". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mease *et al.* (US 6,201,022 B1), McClung (US 6,579,543 B1) and Murad (US 2003/0007930) for reasons set forth in the previous Office action which are restated below. Applicant's arguments filed July 14, 2006 have been fully considered but they are not persuasive.

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Mease *et al.* (US 6,201,022 B1) discloses a composition with omega-3, that contains eiosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and gamma-linolenic acid (GLA)), a pharmaceutical acceptable carrier such as cocoa butter and vitamin E (i.e. tocopherols) to be used in a composition for treating neuritic pain syndrome such as brought on by burns (column 3, lines 62-67; column 4, lines 57-67 and column 5, lines 2-8, 53-55; Table 2 and Example 11). Mease *et al.* do not disclose using lavender oil, Sodium PCA or Methyl-Sulfonyl-Methane.

McClung (US 6,579,543 B1) discloses a composition to be applied for relief of pain brought and by burns and sunburns. The composition contains methyl-sulfonyl-methane (MSM) lavender and omega-3 (column 2, lines 25-35, 67; column 3, lines 46-56; column 4, lines 16-46; column 17, lines 22-23, 55).

Murad (US 2003/0007930) discloses a topical composition for dermatological conditions caused by aging or by extrinsic factors such as sunlight or radiation and wrinkles and sun damaged skin. The composition contains hydrophobic agents such as tocopherols (vitamin E) and moisturizing agents such as sodium PCA and omega-3 which contains gamma-linolenic acid ([0043], 0044], [0053], [0054], [0055]).

These references taken together disclose a composition that comprises omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane that can be used to relieve pain due to burns. Thus, a person of ordinary skill in the art would reasonably expect that omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane would be used to relieve pain from burns as taught by the references. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to modify the teachings of the references.

These references show that it was well known in the art at the time of the invention to use omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane in compositions that aid in relief from burns and other dermatitis conditions. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used

individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane are used in compositions that aid in relief from burns and other dermatitis conditions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions aid in relief from burns and other dermatitis conditions. Therefore, the artisan would have been motivated to combine omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re* Sussman, 1943 C.D. 518; *In re* Huellmantel 139 USPQ 496; *In re* Crockett 126 USPQ 186.

The references also do not specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues (page 9) that the Examiner suggest that those cited patents should not have been granted because they also used known ingredients with known properties? It is noted to Applicant that each patent application was examined on its own merits by the Examiner of record.

Applicant argues (page 9) the Examiner provides no evidence to show why a person skilled in the art would be motivated to combine those specific ingredients together than that they are known and have known properties. This is not found persuasive because as disclosed in

the rejection stated "an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions aid in relief from burns and other dermatitis conditions. Therefore, the artisan would have been motivated to combine omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane into a single composition." In addition, all these are related to dermatitis and burn relief so one of skill would be motivated to combine these ingredients into a single combination.

In response to **Applicant's argument** (page 9-10) that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues (page 13) that the cited references predominantly used plant fatty acids, such as GLA, rather than those from fish oil (EPA, DHA). Specifically, McClung did not include fish oils in any examples. Murad did not use fish oils in any of 14 examples and contain plant GLA as their source of omega fatty acids. In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With regards to plant GLA as a source of omega fatty acids, it is noted to Applicant the specification discloses that GLA is obtained from borage oil (i.e. plant) (page 11, [0031]) and not necessarily from fish oils. As discussed *supra*, Mease discloses omega-3 fatty acids (i.e. EPA and DHA) are obtained from marine sources (i.e. fish) and omega-6 (i.e. GLA) are derived from plant sources (column 3, lines 42-44). In addition, Mease discloses that the topical composition may comprise a mixture of one or more omega-3 and one or more of omega-6 fatty acids (column 4, lines 55-56). Murad discloses hydrophobic agents such as tocopherols (i.e. vitamin E), moisturizing agents such as sodium PCA and omega-3, which contains gamma-linolenic acid. McClung discloses methyl-sulfonyl-methane (i.e. MSM) and lavender oil. The rejection is based on combinations of references.

Applicant argues (page 15) that the cited compositions of McClung and Mease disclose to alleviate pain while Applicant's combination heals or prevents the injury or condition. In response to that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., heals or prevents the injury or condition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant claims that omega-3 fish oils, mixed tocopherols and lavender oil soothes traumatic conditions of the skin and not necessarily *prevents* any traumatic conditions of the skin. Applicant does not discuss the known means for preventing traumatic conditions of the skin. It is well known that it is not possible to completely prevent traumatic conditions of the skin such as exposure-induced wrinkles. "Prevention" of skin conditions requires prevention of each and every instances of exposure. Such prevention is difficult, if not impossible, to achieve. Applicant is requested to note that it is

regarded that "intended use" of a composition or product (e.g. a composition for soothing traumatic conditions of the skin) will not further limit claims drawn to a composition or product. See, e.g., *Ex Parte Masham*, 2 USPQ2d 1647 (1987) and *In Re Hack* 114, USPQ 161. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues (page 16) that Applicant's compositions all contain mixed tocopherols, which are not even mentioned by any of the cited references. Applicant is directed to page 11, [0032] of the specification which states "Vitamin E is a mixture of tocopherols." As disclosed in Mease (column 5, lines 53-55) and Murad ([0053]) vitamin E is used in the cited reference's composition for the treatment of dermatological condition.

Therefore, the rejection is deemed proper and is maintained.

Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

CHRISTOPHER R. TATE
PRIMARY EXAMINER